



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Original 5/24/99 # HFI-35

Public Health Service

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Food and Drug Administration
New Orleans District
Southeast Region
4298 Elysian Fields Ave.
New Orleans, LA 70122

Telephone: 504-589-6341
FAX: 504-589-6360

May 18, 1999

WARNING LETTER NO. 99-NOL-29

OVERNIGHT DELIVERY
FEDERAL EXPRESS

Mr. Brent C. Gutierrez, President
Custom Pack, Inc.
555 Bayview Avenue
Biloxi, Mississippi 39530

Dear Mr. Gutierrez:

On March 17-18, 1999, an FDA investigator conducted an inspection of your shrimp and fish dock, located at 555 Bayview Avenue, Biloxi, Mississippi. The inspection was conducted to determine compliance with FDA's seafood processing regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123) and the Current Good Manufacturing Practice (CGMP) regulations for foods (21 CFR 110).

The seafood processing regulations, which became effective on December 18, 1997, require that you implement a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP essentially involves: (1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having controls at "critical control points" in the processing operation to eliminate or minimize the likelihood that the identified hazards will occur. These are the kinds of measures that prudent processors already take. HACCP provides a systematic way of taking those measures that demonstrates to us, to your customers, and to consumers, that you are routinely practicing food safety by design. Seafood processors that have been fully operating HACCP systems advise us that they benefit from it in several ways, including having a more safety oriented workforce, having less product waste, and having fewer problems generally.

During the March 1999 inspection, the FDA investigator observed shortcomings in your system that were identical to those pointed out in the September 1-2, 1998, inspection and stated in the untitled letter sent to your firm on November 9, 1998. The FDA investigator also provided your firm with a copy of the Domestic Seafood HACCP Report (Form FDA-3501) and the Form FDA-483, which presents his evaluation of your firm's performance regarding various aspects of the HACCP and CGMP requirements. The form FDA-483 is enclosed for your review. The observations of concern to us are as follows:

- (1) Failure to have and implement a written HACCP plan to address the hazards associated with IQF shrimp products, as required per 21 CFR 123.6 (b); and,
- (2) Failure to implement a HACCP plan to address the potential hazard of pathogen growth and toxin formation as a result of time and temperature abuse for the cooked shrimp product, as required by 21 CFR, Part 123.6(b).

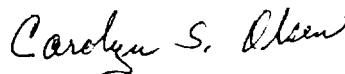
As the principal corporate officer, it is your responsibility to assure that your processing plant is operating in compliance with the applicable laws and regulations. It is also your responsibility to assure not only that the current objectionable conditions are corrected, but that adequate policies and procedures are implemented to prevent a recurrence of the problems.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the applicable regulations. You should take prompt action to correct these deviations. Failure to promptly correct the deviations may result in regulatory action without further notice. These include seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Your reply, relating to these concerns, should be addressed to the U.S. Food and Drug Administration, Attention: Patricia K. Schafer, Compliance Officer, 4298 Elysian Fields Avenue, New Orleans, Louisiana 70122-3896. If you have any questions regarding the implementation of the HACCP regulations, you may contact Ms. Schafer at (504) 589-7166.

Sincerely,



for James E. Gamet
District Director
New Orleans District

Enclosure: FDA-483